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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/812,945 03/27/01 LAN-HARGEST

H 12938-002001

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HM22/1106

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EXAMINER

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

11/06/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/812,945

Applicant(s)

LAN-HARGEST ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,9,11,13,16,19-39 and 47-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,10,12,17,18 and 40-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-43, drawn to a method of inhibiting histone deacetylation in cells, thereby treating a disorder, classified in class 514, subclass 575+.
- II. Claims 47-53, drawn to a method of inhibiting histone deacetylation in cells, classified in class 514, subclass 575+.
- III. Claims 54-66, drawn to a method of treating histone deacetylation mediated disorder, classified in class 514, subclass 575+.

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions have different functions.

Specie election

Claims 1-66 are generic to a plurality of disclosed patentably distinct species of formula I compounds. Claims 1-66 as presented contain such a vast multitude of possibilities and permutations of formula I compounds in that the search for each and every species encompassed in the claims presents an undue burden on the office. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided for in MPEP 803.02. These species are considered to be distinct inventions since the species are so diverse and unrelated structurally that a reference anticipating one of the species would not

anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, **one specific compound**, even though this requirement is traversed.

Claims 1-66 are generic to a plurality of disclosed patentably distinct species comprising histone deacylation mediated disorders or condition e.g., cancer, hemoglobinopathies, hair growth, wound healing, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The treatment of each disorder or condition that can be treated by histone deacylation inhibitors represents a separate field of medical technology having a separate field of search. The search for treatment of all disorder or condition that can be treated by histone deacylation inhibition is therefore an undue burden on the office. Note that the search is not limited to patent files.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Harold Fox on November 1, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-46 and the

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following species: 7-phenyl-2,4,6-hepta-trienoylhydroxamic acid as the elected compound and cancer as the elected disorder. Affirmation of this election must be made by applicant in replying to this Office action. Claims 47-66 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, claims 3, 8-9, 11, 13, 16, 19-39 are withdrawn as being drawn to non-elected species.

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are herein examined on the merits. The claims are examined in so far as they read on the elected species.

Claim Rejections - 35 USC § 101

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility.

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a ^{credible} *** asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some types of cancer, does not reasonably provide enablement for "treating cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

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invention commensurate in scope with these claims. Given the current state of the art, the treatment of all cancers broadly is unpredictable. One of ordinary skill in the art would not believe that one compound could treat all types of cancer with a single therapeutic agent. Decisional law would seem to indicate that when the utility in question is sufficiently unusual an examiner is justified in requiring substantiating evidence, *In re Buting*, 163 USPQ 689 (1969). Moreover, one of ordinary skill in the art would not know which cancers could appropriately be treated with the claimed compounds and would be required to perform undue experimentation to determine the effectiveness and suitability of the claimed compounds in the treatment of different types of cancer. The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richon et al. and Marks et al.

Richon et al. teaches that hydroxamic acid derivatives, a class of hybrid bipolar compounds (HPCs) induce terminal differentiation and or apoptosis in various transformed cells, see abstract.

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Marks et al. teaches that hydroxamic acid-based HPCs are potentially effective agents for cancer therapy, see abstract (reference FF of IDS).

Richon et al. and Marks et al. do not explicitly teach the elected compound in their method of treating cancer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound in a method of treating cancer.

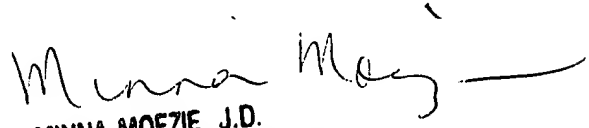
One of ordinary skill in the art would have been motivated to employ the elected compound in a method of treating cancer because the elected compound is a hydroxamic acid derivative. The Skilled Artisan would reasonably expect the elected compound, a derivative of hydroxamic acid to exhibit therapeutic effects similar to hydroxamic acid because structurally related compounds would have been expected to have similar therapeutic effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
November 5, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600